

**Congress of the United States**  
**Washington, DC 20515**

April 9, 2008

Ambassador Susan C. Schwab  
United States Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, DC 20508

Dear Ambassador Schwab:

As you conduct the annual “Special 301” review of the global state of intellectual property rights (IPR) protection and enforcement, we ask you to pay close attention to issues related to public health and access to medicines. Specifically, in determining whether a public health measure raises concerns regarding the “adequate and effective” protection of intellectual property rights, you should consider not only the extent to which greater property rights and protections could enhance innovation, but also the United States’ commitment to respecting measures that improve access to life-saving medicines in developing countries .


A particular concern we have relates to the issuance of compulsory licenses for medicines. In the 2007 Special 301 Report, you downgraded Thailand to the “Priority Watch List,” shortly after it issued compulsory licenses on three pharmaceutical products. The Report included a discussion of concerns about enforcement of copyright and other intellectual property laws, as well as a discussion of the compulsory licenses. The Report appeared to express concern with a perceived “lack of transparency and due process” that occurred when Thailand issued the licenses. Unfortunately, ambiguity in that language has led some to interpret the Report as condemning the issuance of compulsory licenses as inherently indicative of a weakened respect for patents.

As you know, the use of compulsory licenses, with “adequate remuneration” paid to the patentholder, is permitted by the WTO Agreement on Trade-Related Aspects of Intellectual Property (the “TRIPS Agreement”). In the 2001 Doha Declaration, the United States and the other 142 WTO Members committed to respecting “the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement,” which provide “flexibilities” to enable a Member “to protect public health and, in particular, to promote access to medicines for all.” One crucial flexibility is that each Member has “the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”


We are concerned that USTR’s recently released 2008 National Trade Estimate (NTE) Report on Foreign Trade Barriers inaccurately characterizes Thailand’s authority to issue compulsory licenses. The NTE states that “The United States acknowledges Thailand’s ability to issue compulsory licenses to address public health emergencies, subject to Thailand’s domestic and international legal obligations as a WTO Member.” In fact, TRIPS does not limit compulsory licenses to “emergencies,” but rather, as discussed above, permits countries to determine when they are necessary.

In the upcoming Special 301 report, we urge you to reaffirm, and to act upon, the commitment the United States made in the Doha Declaration. While other factors may affect the ultimate determination made in a 301 report – and we urge you to consider any progress made in those factors as appropriate - countries should not be cited for the use of compulsory licenses or other flexibilities in accordance with international trade rules.


Sincerely,



HENRY A. WAXMAN  
Member of Congress




THOMAS H. ALLEN  
Member of Congress



JOHN LEWIS  
Member of Congress



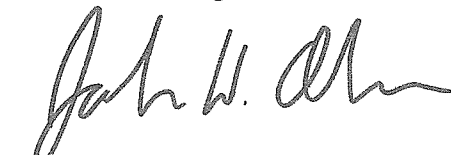
EARL BLUMENAUER  
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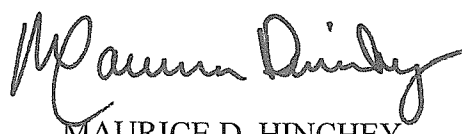
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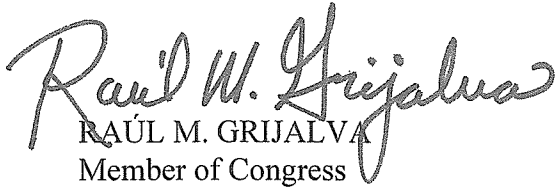
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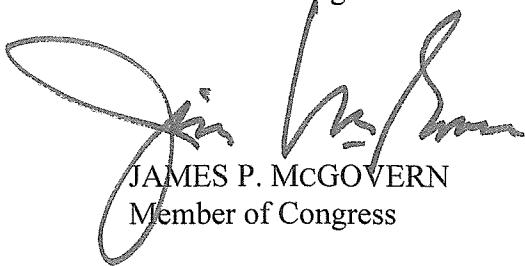
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